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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, BAO THUY L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/076,596	Applicant(s) MINK ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,53-55 and 57-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1,53-55 and 57-78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment dated 11 July 2008 has been received.
2. Claims 2-52 and 56 have been canceled. Claims 72-78 have been added. Claims 1, 53-55 and 57-78 are pending.
3. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 53-55, 57, 60-72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over May (US 5,622,871) in view of Schlipfenbacher (US 5,160,486).

May discloses a device comprising a housing (500) and a strip (506, 510), the strip comprising a collection strip (506) in fluid communication with a lateral flow assay strip (510), wherein the lateral flow assay strip (510) is contained substantially within the housing, contains at least one blocking agent or buffer (see col. 16 line 67 to col. 17 line 40), contains at least one reagent used to detect the presence or absence of an antibody (see col. 16, lines 59-65), contains one or more zones that indicate the presence or absence of the antibody (see col. 19, lines 57-65). The collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a source to the assay strip (see col. 18, lines 35-40). May specifically teaches that the sample receiving

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member can be made from any bibulous, porous or fibrous material capable of absorbing liquid rapidly. May teaches porous plastic material such as polypropylene, polyethylene, polyvinylidene fluoride, ethylene vinylacetate, etc. May also teaches treating the member with a surface active agent to enhance its ability to take up and deliver a moist sample rapidly and efficiently. See column 4, lines 43-57. May specifically teaches that materials such as used in the nibs of fibre tipped pens are *particularly* suitable and such materials can be shaped or extruded in a variety of lengths and cross-section as appropriate. See column 4, lines 59-63. Regarding claim 61, the collection strip protrudes from the housing and is a paddle-shape (see Figs. 8 and 9). The lateral flow assay strip is an immunochromatography strip (see col. 15, lines 4-34). The reagent is a binding partner that bears a detectable label (see col. 15, line 35 to col. 17 line 15). May teaches the detection of hormones such as LH and hCG, bacterial agents such as streptococcus and Chlamydia, as well as steroids and drugs and specifically state that the device may be modified to determine a wide variety of analytes by choice of appropriate specific binding reagents. See column 9, lines 14-25. Regarding claims 68 and 69, May ('871) discloses a kit comprising the device discussed above and separately a buffer or reagent (see col. 4, lines 38-42).

May differs from the instant invention in failing to specifically teach a separate blocking strip and a conjugate strip between the collection strip and assay strip.

Schlipfenbacher ('486) teaches providing a blocking strip (23) containing a buffer and a conjugate strip (24) between a collection strip and an assay strip. See column 8, lines 23-31. The reagents in the blocking strip 23 comprise sodium phosphate and bovine serum albumin to prevent non-specific binding. See column 11, lines 1-11.

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It would have been obvious to one of ordinary skill in the art to modify the device of May by providing a blocking strip and conjugate strip between the collection strip and assay strip as taught by Schlipfenbacher ('486) because Schlipfenbacher ('486) expressly teaches providing the strips as an alternative to merely having corresponding separate zones of a single strip (see Fig. 1 vs. Fig. 2). With respect to the recitation of a non-absorbing sample collection strip, May teaches the same materials as those disclosed in the specification, therefore, the sample absorbing strip of May is seen to have the same inherent characteristics as that of the instant claims. With respect to the recitation of a planar flow communication, May teaches lateral flow and thus it is seen to be the same with planar flow.

6. Claims 58, 59, 73, 74 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Schlipfenbacher as applied to claims 1 and 53-55, 57, 60-72 and 75 above, and further in view of Guan et al (US 2001/0023076).

May and Schlipfenbacher differ from the instant invention in failing to teach a device comprising antigens or antibodies to HIV or hepatitis.

Guan, however, discloses devices, kits and method for the detection a variety of analytes including HIV and hepatitis. Guan teaches that analytes such as antigens or antibodies to HIV and hepatitis may be detected using appropriate capture reagents. See paragraphs [0052], [0054] and [0076].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of May as taught by Schlipfenbacher to includes appropriate reagents to detect analytes such as HIV and hepatitis as taught by Guan because May

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specifically teaches that its device may be used to determine a variety of analytes by choice of appropriate reagents.

Response to Arguments

7. Applicant's arguments filed 11 July 2008 have been fully considered but they are not persuasive.

Applicant argues that May does not teach blocking strip and does not teach or suggest applying blocking agents to any portion of the lateral flow strip. And that a particularly cited passage is not concerned with non-specific binding to the lateral flow strip.

This argument is not persuasive. May specifically teaches applying blocking agents to the lateral flow test strip to prevent non-specific binding. See column 6, lines 45-57. The citation of one specific passage in the May reference to support this argument is also not persuasive because references must be considered as a whole. A piecemeal analysis is not persuasive.

The argument that the non-specific treatment method of May is not equivalent to the instant claims because it requires time, cost and potential errors because it involves at least 8 steps and numerous reagents is not persuasive.

The instant claims are directed to an apparatus comprising a blocking strip having a blocking agent such as BSA, for example, and not to a method of making such a strip. Therefore, regardless of how the product is made, if the resulting product is the same as that of the prior art then it is anticipated or is obvious over the prior art. In the instant case, Schlipfenbacher discloses a blocking strip (23) containing a buffer disposed between a collection strip and an

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assay strip (column 8, lines 23-31) comprising sodium phosphate and bovine serum albumin to prevent non-specific binding (column 11, lines 1-11). Therefore, a skilled artisan would have had a reasonable expectation of success in modifying the device of May by providing for a blocking strip and conjugate strip between the collection strip and assay strip as taught by Schlipfenbacher ('486) because Schlipfenbacher ('486) expressly teaches providing the strips as an alternative to merely having corresponding separate zones of a single strip (see Fig. 1 vs. Fig. 2). It is also well known in the art to having a blocking strip comprising a buffer or other auxiliary reagents adjacent to the sample application zone to provide the advantage of adjusting the pH value of the sample to the requirement of the test. See Schlipfenbacher column 2, lines 45-54.

The argument that the instant capillary matrix is distinguishable from May because May teaches devices related to urine samples and not oral samples, is not persuasive.

The instant capillary matrix is disclosed in the specification as porous matrices of a high density polyethylene (HDPE), or polyethylene or PVDF for example, which are the same as those taught by May at column 4, lines 43-57. May teaches porous plastic material such as polypropylene, polyethylene, polyvinylidene fluoride, ethylene vinylacetate, etc, therefore, the capillary matrix taught by May is expected to have the same inherent property as those of the instant invention. The intended use of the instant matrix does not change the matrix itself nor its inherent characteristics.

The argument that the matrix taught by May is pre-treated during manufacture which is different from the treatment of the instant invention is not persuasive. The instant claims are not directed to the treatment of the matrix. The instant claim only requires an essentially non-

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absorbing capillary matrix extending from within the housing and protruding out from the housing. This matrix is clearly taught by May. The intended use of this matrix is not given patentable weight as noted above.

The argument that the instant matrix prevents backflow is not persuasive. This limitation is not recited in the claims. Applicant is reminded that although the claims are read in light of the specification, limitations in the specifications are not read into the claims. Furthermore, since the instant matrix and those taught by May are made of the same material, they would be expected to have the same inherent properties.

The argument that Schlipfenbacher teaches away from the instant invention is not persuasive. Schlipfenbacher is cited for its teaching that an auxiliary strip comprising buffer and non-specific blocking agents disposed between a collection strip and an assay strip is well known in the art and provides the advantage of adjusting the pH value of the sample to the requirement of the test and to prevent non-specific binding of components to the lateral flow matrix.

The argument that Schlipfenbacher does not teach the collection of oral fluid is not persuasive because intended uses are not given patentable weight.

The argument that it is not clear what is contained on the auxiliary reagent zone is not persuasive. Schlipfenbacher specifically teaches that the auxiliary reagent zone comprises buffer to adjust the pH value of the sample to the requirement of the test, wetting agents and the like. Column 2, lines 48-52. Schlipfenbacher also teaches in one specific embodiment BSA and sodium phosphate buffer impregnated in the zone.

The argument that there is no indication of the function of the BSA is not persuasive. May specifically states that BSA is a reagent that is well known in the art for use in blocking non-

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specific binding (column 10, lines 29-34), therefore, a skilled artisan would have had a reasonable expectation of success in using BSA to prevent non-specific binding as taught by both May and Schlipfenbacher. Furthermore, since the reagent for preventing non-specific binding recited in the instant claims and that disclosed by Schlipfenbacher is the same, i.e. BSA, they would be expected to have the same inherent properties.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
16 October 2008